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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,756	08/02/2005	Andreas Brunner	U 015531-8	1331

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,756	BRUNNER ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1. The Preliminary Amendments filed on December 13, 2004 have been entered by the office. The claims pending in this application are claims 30-66.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 30-36, drawn to a method for the identification of tissue/cell specific maker genes.

Group II, claims 37-48, drawn to a method for the quality control of tissue biopsies and/or cells/tissue cultivated/produced *in vitro* (claims 37-46) and a method for the determination of characteristic gene expression profiles for clinical use.

Group III, claims 49-64, drawn to a cartilage array (claims 49-62) and a kit comprising a cartilage array (claims 63 and 64), use of a cartilage array (claim 65), and use of a kit (claim 66).

3. The inventions listed as Groups I to III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I and Groups II and III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, the technical feature linking Group I and Groups II and III is not special since the method recited in claim 1 is not contribution over the prior art (see Stokes et al., Arthritis & Rheumatism, 46, 404-419, February 2002 from IDS filed on December 13, 2004).

Group II and Groups III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, comparison of said resulting profile with profiles characteristic for a particular status or physiological potential of the examined cells/tissue and determination of the particular status of the examined tissue/cells of claim 37 in Group II is not required for Group III while the kit in Group III is not required for Group II.

Gene Election Requirement Applicable to Group III

Claims 53 and 58 in Group III read on patentably distinct 467 different genes. Each gene is patentably distinct because these genes are structurally unrelated. Therefore, applicant must further elect a single combination consisting of at least part of the cartilage marker genes from 467 different genes in the specification. Applicant is advised that examination will be restricted to only elected combination and should not to be construed as a species election.

4. Group II contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) for the use in diagnosis within clinical applications and gene expression profiles used as a diagnostic tool therein by assessing patient biopsy/cell samples for functionality, culturing functional cells in an in vitro cell culture to get cultured cells/tissue for the treatment/ performance in a cell or tissue based therapy (claim 43)

(2) for the use in diagnosis within clinical applications and gene expression profiles used as a diagnostic tool therein by assessing patient biopsy/cell samples and deciding on a subsequent therapeutic approach, said approach preferably being selected from the group consisting of tissue engineered therapy, cell therapy, and traditional surgical approach (claim 44)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic claims: claims 37-42 and 45-48.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

assessing patient biopsy/cell samples for functionality, culturing functional cells in an in vitro cell culture to get cultured cells/tissue for the treatment/ performance in a cell or tissue based therapy in species (1) is not required for species (2) while assessing patient biopsy/cell samples and deciding on a subsequent therapeutic approach, said approach preferably being selected from the group consisting of tissue engineered therapy, cell therapy, and traditional surgical approach in species (2) is not required for species (1).

5. Group II further contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(3) for the use in quality control and gene expression profiles used as a quality control tool therein by assessing the quality of human biopsy/cell samples (claim 45)

(4) for the use in quality control and gene expression profiles used as a quality control tool therein by assessing the quality of the final implant prior and/or after product release (claim 46)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic claims: claims 37-44, 47, and 48.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

assessing the quality of human biopsy/cell samples in species (3) is not required for species (4) while assessing the quality of the final implant prior and/or after product release in species (4) is not required for species (3).

6. Group III contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(5) the cartilage array of claim 49 is used within clinical applications as a diagnostic tool in order to assess patient biopsy/cell samples for targeted in vitro cell culture treatment/ performance when performing a cell or tissue based therapy (claim 59)

(6) the cartilage array of claim 49 is used within clinical applications as a diagnostic tool in order to assess patient biopsy/cell samples and to decide on subsequent therapeutic approach

which maybe a tissue engineered therapy, a cell therapy only, or even a traditional surgical approach only (claim 60)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic claims: claims 49-58 and 61-63.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

assessing patient biopsy/cell samples for targeted in vitro cell culture treatment/ performance when performing a cell or tissue based therapy in species (5) is not required for species (6) while assessing patient biopsy/cell samples and to decide on subsequent therapeutic approach which maybe a tissue engineered therapy, a cell therapy only, or even a traditional surgical approach only in species (6) is not required for species (5).

7. Group III further contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(7) the cartilage array of claim 49 is used as a quality control tool in order to assess the quality of human biopsy/cell samples (claim 61)

(8) the cartilage array of claim 49 is used as a quality control tool in order to assess the quality of the final implant prior and/or after product release (claim 62)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic claims: claims 49-60 and 63.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

assessing the quality of human biopsy/cell samples in species (7) is not required for species (8) while assessing the quality of human biopsy/cell samples in species (8) is not required for species (7).

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571) 272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 13, 2007

FRANK LU
PRIMARY EXAMINER